IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	:	Master Docket: Misc. No. 21-mc-1230-JFC
	:	
	:	MDL No. 3014
This Document Relates to: All Actions	:	

RICO CASE STATEMENT PURSUANT TO LCvR 7.1.B FOR PLAINTIFFS' CONSOLIDATED THIRD AMENDED CLASS ACTION COMPLAINT FOR ECONOMIC LOSSES

Pursuant to LCvR 7.1.B, any party filing a civil action under 18 U.S.C. §§ 1961-1968 shall set forth those facts upon which such party relied to initiate the RICO claim as a result of the "reasonable inquiry" required by Fed. R. Civ. P. 11. The statement shall be in paragraph form corresponding by number and letter to the paragraphs and subparagraphs appearing below and shall provide in detail and with specificity the information required herein.

1. **State whether the alleged unlawful conduct is in violation of any or all of the provisions of 18 U.S.C. §§ 1962(a), (b), (c) or (d).** Plaintiffs bring RICO claims based on alleged violations of 18 U.S.C. §§ 1962(c) & (d).

2. **List each defendant and state the alleged misconduct and basis of liability of each defendant.** The "RICO Defendants" include Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation (collectively, "Philips"), and Polymer Technologies, Inc. and Polymer Molded Products LLC (collectively, "PolyTech").

Philips and PolyTech conducted or participated in the affairs of an "association-in-fact enterprise"—*i.e.*, the Philips-PolyTech Enterprise—through a pattern of racketeering activity

(stemming from the predicate racketeering acts of mail and wire fraud) in violation of 18 U.S.C. § 1962(c). The Philips-PolyTech Enterprise engaged in this pattern of illegal activities in furtherance of its common purpose to unlawfully defraud and mislead, among others, the FDA, prescribers, third-party payors ("TPPs"), patients, hospitals, and consumers about the safety of the Recalled Devices.[1] In so doing, each of the RICO Defendants knowingly caused or participated in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

Each RICO Defendant participated in the Philips-PolyTech Enterprise and played a distinct role in furthering the enterprise's common purpose of knowingly concealing information about the safety of the Recalled Devices to increase profits.

Specifically, the RICO Defendants worked together to coordinate the enterprise's goals, conceal the existence of the enterprise, and conceal their individual roles within it. Further, each of the RICO Defendants were linked through their business relationships and continuing coordination of activities. These business relationships facilitated the formation of a common purpose among the RICO Defendants, who each agreed to participate in the conduct of the Philips-PolyTech Enterprise. Specifically, each RICO Defendant played a critical role in producing the Recalled Devices, concealing the Recalled Devices' defective condition, and selling the Recalled Devices.

At all relevant times, the Philips-PolyTech Enterprise: (i) had an existence that was separate and distinct from the individual RICO Defendants and their members; (ii) was separate and distinct from the pattern of racketeering in which the individual RICO Defendants engaged; (iii) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including

[1] "Recalled Devices" are defined in the Consolidated Third Amended Class Action Complaint for Economic Losses (ECF 785) as the CPAP and BiPAP devices, and mechanical ventilators recalled by Philips on June 14, 2021: E30; DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV, S/T, AVAPs; OmniLab Advanced Plus; SystemOne (Q Series); DreamStation CPAP, Auto CPAP, BiPAP; DreamStation Go CPAP, APAP; Dorma 400, 500 CPAP; REMStar SE Auto CPAP; Trilogy 100 and 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30; A-Series BiPAP V30 Auto; A-Series BiPAP A40; and A-Series BiPAP A30.

each of the RICO Defendants; (iv) was characterized by relationships between and among each RICO Defendant; and (v) had sufficient longevity for the enterprise to pursue its common purpose and function as a unit.

The RICO Defendants participated in the conduct of the Philips-PolyTech Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud). This was done to increase and maintain profits by hiding and misrepresenting the dangers associated with the Recalled Devices.

Each of the Recalled Devices contains PE-PUR foam which Philips has admitted "may break down into particles and be inhaled or ingested, or may emit volatile organic compounds ('VOCs') that may be inhaled, resulting in 'serious injury, which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.'"[2] The Philips-PolyTech Enterprise came together for the common purpose of perpetuating a fraudulent scheme to conceal the true health and safety risks associated with the Recalled Devices and PE-PUR foam from patients, prescribers, TPPs, hospitals, and the FDA This concealment was intended to allow the enterprise participants to profit, continue to profit, and retain profits from the sale and lease of Recalled Devices.

By knowingly concealing and minimizing the Defect, the RICO Defendants could represent the Recalled Devices as being safe and effective while omitting information to the contrary. These false representations, half-truths, and related omissions resulted in significant sales and revenue generated from the sale of defective Recalled Devices. Concealing and minimizing the Defect also allowed the RICO Defendants to avoid or limit the substantial costs and reputational harm associated with a recall, repair or replacement of the Recalled Devices.

[2] *See* Consolidated Third Amended Class Action Complaint for Economic Losses, ¶ 9. Plaintiffs refer to this degradation and off-gassing, and the resulting health effects, as the "Defect" in the Recalled Devices.

Each of the RICO Defendants profited, directly and indirectly, from the scheme. These profits were substantially greater than they would have been if the Defect and true risks of the Recalled Devices had been disclosed. Because the RICO Defendants' ability to profit from this scheme depended on the using, prescribing, selling, and/or leasing of the Recalled Devices, the Philips-PolyTech Enterprise needed to ensure complete allegiance to a false premise: that the Recalled Devices were safe and effective. For this scheme to work, it was essential for the Philips-PolyTech Enterprise to conceal the Defect from the FDA because the agency could otherwise investigate, recall the devices, and notify the public of the Defect. The expense of a recall and the resulting inability to sell the defective Recalled Devices would undermine the profitability of the scheme.

3. **List alleged wrongdoers, other than the defendants listed above, and state the alleged misconduct of each.** During the relevant period, Paramount Die Corporation: (1) contemporaneously provided cutting services for rubber, foam, plastic, and other materials apart from the PE-PUR foam used in the Recalled Devices; (2) actively participated in the production, marketing, and selling of the defective Recalled Devices, and along with the other members of the Philips-PolyTech Enterprise, did not disclose the Defect in those devices; (3) like the RICO Defendants, profited from the sale and lease of the Recalled Devices that contained the PE-PUR foam modified by Paramount Die for use in the Recalled Devices. Discovery will likely reveal additional members of the RICO Defendants' Enterprise that are not currently known to Plaintiffs.

4. **List the alleged victims and state how each victim has been allegedly injured.** The victims include all the named Plaintiffs and members of the putative Nationwide Class and Subclasses, which include all persons or entities (including consumers, institutions, insurers, self-funded employers, and TPPs) in the United States (including its Territories and the District of Columbia) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

These victims were injured in their business and/or property by paying for or reimbursing payment for Recalled Devices with an undisclosed safety defect. The Philips-PolyTech Enterprise directly or indirectly obtained money from Plaintiffs and the Class by means of materially false or fraudulent misrepresentations and omissions of material facts. Had the Plaintiffs and Class members known what the RICO Defendants knew about the Recalled Devices, they would not have paid for or reimbursed payment for the Recalled Devices. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused injury to Plaintiffs' and Class members' business and property. The RICO Defendants' pattern of racketeering activity logically, substantially, and foreseeably caused TPPs, hospitals, and consumers to pay for or reimburse payment for the Recalled Devices. The injuries suffered by the Plaintiffs and Class members were not unexpected, unforeseen, or independent. Rather, the RICO Defendants knew that the Recalled Devices were defective and unsafe. Notwithstanding their knowledge of these risks, the RICO Defendants used mail and wires to further and carry out their scheme of deception, thereby reaping increased profits. Had the RICO Defendants disclosed their knowledge of the Defect in the Recalled Devices and informed the FDA and the public, Plaintiffs and Class members would have learned of the disclosure and made informed decisions about the health and safety risks of the Recalled Devices. The Enterprise's misleading statements and omissions to the FDA and to prescribers were essential to the scheme. The FDA would have considered information about the defective PE-PUR foam material (as evidenced by its Class I classification of the ongoing recall), and prescribers would not have prescribed dangerous and defective breathing machines to their patients. At the very least, the RICO Defendants' misleading statements and omissions delayed the FDA's broader investigation of the Recalled Devices. The RICO Defendants knew that their concealment of the risks would cause Plaintiffs and the Class to pay for or reimburse payment for the Recalled Devices and to the extent they are the users of the Recalled Devices, to suffer the attendant harms and safety risks of breathing

through machines with defective and toxic foam.

5. **Describe in detail the pattern of racketeering activity or collection of unlawful debts alleged for each RICO claim. The description of the pattern of racketeering shall include the following information:**

a. A list of the alleged predicate acts and the specific statutes which were allegedly violated. In furtherance of the scheme, the RICO Defendants knowingly conducted or participated, directly or indirectly, in the Philips-PolyTech Enterprise through racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c). Specifically, the RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity within, approximately, the past ten years, therefore constituting a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels and employees of the Philips-PolyTech Enterprise, the U.S. Mail and interstate wire facilities. The RICO Defendants participated in the scheme to defraud by using mail, telephones and Internet to transmit mailings and wires in interstate or foreign commerce. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of the enterprise's objectives through misrepresentations, concealments, and material omissions. The RICO Defendants caused such mailings and uses of wires to be made either by directly making or approving certain fraudulent statements or by setting in motion a scheme to defraud that would reasonably lead to those mailings and wirings.

The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. Mail or commercial

interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the Recalled Devices by means of false pretenses, misrepresentations, promises, and omissions.

- Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

The RICO Defendants' uses of the mails and wires include, but are not limited to, the transmission, delivery, or shipment of the following by the RICO Defendants or third parties that were foreseeably caused to be sent in furtherance and as a result of the RICO Defendants' illegal scheme to defraud:[3]

- Shipments by Philips of the Recalled Devices, known by Defendants to be defective, to locations throughout the United States for distribution and sale. Plaintiffs do not have access to the confidential records that provide the precise dates and locations of these shipments, which occurred in each year beginning no later than 2015 and continuing through 2021. The Recalled Devices transported in interstate commerce were misbranded, in violation of 21 U.S.C. § 352.
- Shipments from PolyTech to Philips (including via Paramount Die) of the PE-PUR foam for installation in the Recalled Devices with the knowledge that Philips would use the foam in the defective Recalled Devices and distribute the Recalled Devices throughout the United States using interstate carriers. Plaintiffs do not have access to

[3] Many of the precise dates and examples of the uses of the U.S. Mail and interstate wire facilities to further their fraudulent scheme cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred.

the confidential records that provide the precise dates and locations of these shipments, which occurred in each year beginning no later than 2015 and continuing through 2021.

- Shipments by William T. Burnett & Co. ("Burnett") of bulk PE-PUR foam sheets by private or commercial interstate carrier to PolyTech for use in the Recalled Devices. PolyTech caused Burnett to make these shipments when it ordered the bulk foam, knowing it would then transmit the foam for installation in the Recalled Devices. Plaintiffs do not have access to the confidential records that provide the precise dates and locations of these shipments, which occurred in each year beginning no later than 2015 and continuing through 2021. Documents provided to date from Burnett provide the particulars of at least one such shipment, which originated from Burnett in Baltimore, Maryland and was shipped to PolyTech in Newark, Delaware, on or about March 12, 2021.
- Advertisements, brochures, labeling, and marketing from Philips that omitted the known health and safety risks of the Recalled Devices, distributed using mail, wire, radio, or television communications in interstate commerce. This includes transmission of statements from Philips that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind" and the numerous other misrepresentations related to safety and efficacy cited in the Consolidated Third Amended Class Action Complaint for Economic Losses. *See* ¶¶ 358-359. Each such mailed advertisement—including brochures or print advertisements—violated the mail fraud statute (18 U.S.C. § 1341). Each such internet-based, radio, and television advertisement was a violation of the wire fraud statute (18 U.S.C. § 1343). Philips knew its advertisements about the Recalled Devices were misleading and omitted

material information, but still disseminated the advertisements to ensure the continued prescription and sale of the Recalled Devices.

- Advertisements and marketing from PolyTech for the PE-PUR foam used in the Recalled Devices, including marketing that falsely misrepresented the foam to have "superior physical properties and offer excellent resistance to heat, moisture, and chemicals." Each such mailed advertisement was a violation of the mail fraud statute (18 U.S.C. § 1341). Each such internet-based, radio, and television advertisement was a violation of the wire fraud statute (18 U.S.C. § 1343). PolyTech knew its advertisements were misleading and omitted material information, but still disseminated the advertisements to ensure the continued prescription and sale of the Recalled Devices.
- Documents necessary to facilitate the sale and transmission of bulk PE-PUR foam from Burnett for use in the Recalled Devices, including invoices, packing lists, labels, invoices, and test reports. Each RICO Defendant knew that these documents would foreseeably result in the manufacture and sale of the Recalled Devices, thereby furthering the scheme to continue to make and sell them without disclosing the Defect.
- Documents necessary to facilitate the manufacture and sale of the Recalled Devices, including bills of lading, invoices, shipping records, reports and correspondence. Each of the RICO Defendants knew that these documents would foreseeably result in the manufacture and sale of the Recalled Devices, thereby furthering the scheme to continue to make and sell them without disclosing the Defect.
- Documents necessary to process and receive payment for the Recalled Devices by unsuspecting Plaintiffs and Class members, including invoices and receipts. Each of

the RICO Defendants knew that these documents were the foreseeable result of the manufacture and sale of the Recalled Devices, thereby furthering their scheme to continue to make and sell them without disclosing the Defect.

- False or misleading communications, internally to Philips and PolyTech and externally with third parties, including Burnett, that obscured the Defect and prevented regulators and the public from discovering the true risks of the Recalled Devices, and/or purposely misidentified the cause of issues in the Recalled Devices to external factors, such as ozone cleaners.
- While using mail and wire to defraud and obtain revenue under false pretenses, Philips and PolyTech failed to timely, accurately, and completely disclose the Defect and associated risks in the Recalled Devices when Philips and PolyTech had a duty to disclose this information.

The RICO Defendants (or their agents), in furtherance of their illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of the Recalled Devices and related documents and communications. Because the RICO Defendants disguised their participation in the Enterprise and worked to keep the Enterprise's existence secret so as to give the false impression that the Recalled Devices were safe, many of the precise dates of the Enterprise's use of U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the RICO Defendants' records. Indeed, an essential part of the successful operation of the Philips-PolyTech Enterprise alleged herein depended upon secrecy. However, Plaintiffs describe occasions on which the RICO Defendants disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, and how those acts advanced the scheme. These disseminations include:

From	To	Date	Description
Philips	PolyTech	October 30, 2015	Email message from Philips to PolyTech sharing information and implying that a customer made Philips aware of PE-PUR foam degradation issues.
PolyTech	Burnett	October 30, 2015	Email message from PolyTech to Burnett transmitting information from Philips about PE-PUR foam degradation issues.
Philips entity	Philips	November 25, 2015	Communications transmitting information about a preventative maintenance servicing procedure implemented on Trilogy devices by a Philips entity, which resulted in no documented further investigation, risk analysis, or design review.416[4]
Bob Marsh, PolyTech	Lee Lawler, Burnett	August 5, 2016	Email message from Bob Marsh of PolyTech to Lee Lawler of Burnett, referring to questions from Philips, and admitting that PolyTech would inform Philips of risks of PE- PUR foam raised by Burnett in 2016.

[4] This and other footnote numbers in this Table correspond to those in the Consolidated Third Amended Class Action Complaint for Economic Losses filed on October 10, 2022.

From	To	Date	Description
Philips		April 1, 2016 to January 22, 2021	Documents and communications sharing results of at least fourteen instances, assessments, and/or test reports, where Philips was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices.
Vincent Testa, Philips	Bonnie Peterson, PolyTech	April 20, 2018	Email reporting consumer complaints that PE-PUR foam in Trilogy devices was "disintegrating" and admitting it was a "potential safety concern."
Bob Marsh, PolyTech	Lee Lawler, Burnett	April 23, 2018	Email correspondence regarding degradation of ester foam, and forwarding email from Vince Testa of Philips regarding the same.[417]
Bob Marsh, PolyTech (with Bonnie Peterson and Mike Haupt, PolyTech)	Lee Lawler, Burnett	May 2, 2018 and May 4, 2018	Email correspondence confirming Philips' test results for ether vs. ester foam confirming that ether was the "better performer" but nonetheless raising Philips' and PolyTech's plan to continue using ester foam.[418]
Philips		May 22, 2018	Communications to prepare Philips' Biological Risk Assessment document, which was deemed "inadequate" by the FDA because it did not "accurately reflect known data" about PE-PUR foam degradation in Trilogy ventilator devices.[419]

From	To	Date	Description
Philips		May 2018	Communications to prepare Philips' Health Hazard Evaluation, ER22227646, which was deemed "inadequate" by the FDA because it did not "accurately reflect known data" about PE- PUR foam degradation in Trilogy ventilator devices.
Philips		June 2018	Communications to close CAPA INV 0988 related to Trilogy Devices without reference to other CPAP and BiPAP devices, including the Recalled Devices despite knowledge of consumer complaints of foam degradation in those devices.
Philips		August 24, 2018	Intra-company email amongst Philips personnel discussing testing that confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints received
Philips		December 12, 2018	Communications transmitting test results that acknowledged a "problem of degradation" in PE-PUR foam in Trilogy devices as a result of field reports/complaints, following which "no further design change, corrective action, or field correction was conducted" for the Recalled Devices for at least three years.[420]

From	To	Date	Description
Philips		June 2019	Documents and communications for inadequate formal CAPA 7211 investigation that excluded known medical device reports and complaints.
Philips		April 26, 2021	Press release admitting to serious health risks of the Recalled Devices but misleadingly casting blame on other "factors" such as ozone cleaners.

b. The date of each predicate act, the participants in each such predicate act and the relevant facts surrounding each such predicate act. *See* above.

c. The time, place and contents of each alleged misrepresentation, the identity of persons by whom and to whom such alleged misrepresentation was made and if the predicate act was an offense of wire fraud, mail fraud or fraud in the sale of securities. The "circumstances constituting fraud or mistake" shall be stated with particularity as provided by Fed. R. Civ. P. 9(b). *See* above. The uses of mail and wire described above violated the mail and wire fraud statutes because they furthered a fraudulent scheme to mislead consumers, patients, prescribers, TPPs, hospitals, and the FDA about the Recalled Devices. In addition, these same uses of mail and wire were illegal because, when they sent or caused to be sent, the RICO Defendants had duties to disclose the health and safety risks associated with the Recalled Devices. The RICO Defendants failed to disclose this critical information in order to advance their scheme.

For years, the RICO Defendants each knew of the risks and safety concerns in the Recalled Devices. Specifically, Philips and PolyTech knew by no later than 2015—meaning, at best, six years before a public recall announcement—about foam degradation issues in PE-PUR foam in the field. To further the goals of the Philips-PolyTech Enterprise and to their mutual monetary gain, the RICO

Defendants failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices and continued to manufacture and sell them for years in spite of that knowledge.

The RICO Defendants' careful efforts to conceal the risks of the Recalled Devices were critically important to the viability of their scheme. A decision by any one RICO Defendant to tell the truth about the Defect would have been an existential threat to the Enterprise. Instead, each RICO Defendant kept key information about the risks of the Recalled Devices and known issues hidden for years. This omission of material facts about the Defect occurred because it advanced the RICO Defendants' scheme to sell and continue to profit from defective Recalled Devices and avoid costly recalls and reputational harms.

The RICO Defendants' failure to disclose the known safety risks associated with the Defect in the Recalled Devices violated several independent duties to disclose:

- As a medical device manufacturer, Philips had a duty to disclose material facts about the safety risks of its devices to physicians, patients, and the FDA. This includes Philips' statutory and regulatory duties pursuant to 21 U.S.C. § 352 (FDCA); 21 C.F.R. § 820.70 and 21 C.F.R. § 803.
- The RICO Defendants also each had a duty to disclose the Defect in the Recalled Devices because of their exclusive knowledge and far superior information in their possession. The RICO Defendants knew about the risks to users of the Recalled Devices due to the PE-PUR foam, which they gathered through their exclusive access to information about their design, development, and testing, and through their confidential and proprietary investigations following consumer complaints. Plaintiffs, by contrast, lack the sophisticated expertise that would be necessary to discover the Defect and its implications on their own.
- The RICO Defendants' affirmative steps to conceal the Defect deprived Plaintiffs and

Class members from an opportunity that otherwise could have led to their discovery of the truth. Philips and PolyTech also each had a duty to disclose because of the actions they took to conceal the Defect which was a material fact. Philips acted to suppress the truth including when it inappropriately limited and closed its CAPA investigations (thus avoiding a written record), omitted relevant data from its Biological Risk Assessments, and attempted to blame independent factors such as ozone cleaners for the Defect. PolyTech, for its part, suppressed the truth when it corresponded with Burnett about the known risks of PE-PUR foam and took no action, instead continuing to supply the PE-PUR foam to Philips for use in the Recalled Devices.

- Finally, Philips affirmatively disclosed information about the Recalled Devices such as the information discussed in ¶¶ 358 and 359 in the Consolidated Third Amended Class Action Complaint. Because Philips opted to make these representations, and because it knew other information about the Recalled Devices that made those representations misleading or untrue, Philips was under a separate duty to disclose the full truth about the Defect that materially qualified the information it provided.

The RICO Defendants knew and intended that Plaintiffs would rely on the RICO Defendants' and the other Enterprise members' material omissions when they used, paid for, and/or reimbursed payment for the Recalled Devices. Plaintiffs' reliance on this concealment is demonstrated by the fact that they paid money for or reimbursed payment for defective Recalled Devices that never should have been introduced into the U.S. stream of commerce.

d. Whether there has been a criminal conviction for violation of any predicate act and, if so, a description of each such act. Plaintiffs are not aware of any criminal convictions for violation of any predicate act.

e. Whether civil litigation has resulted in a judgment in regard to any predicate act and, if so, a description of each such act. Plaintiffs are not aware of any civil litigation that has resulted in a judgment as to any predicate yet.

f. A description of how the predicate acts form a "pattern of racketeering activity." Each of the predicate acts detailed above had the common purpose of generating significant revenue and profits for the RICO Defendants from the sale of Recalled Devices. This was accomplished by concealing from patients, users, consumers, prescribers, TPPs, and the FDA the true health risks and the safety defect associated with the Recalled Devices and the PE-PUR foam in the Recalled Devices. Further, this common purpose was served by the above-described instances of the RICO Defendants sharing information and evidence about the Defect among the Enterprise. This sharing of information allowed the RICO Defendants to coordinate their actions and efforts to conceal. The RICO Defendants' pattern of racketeering activity alleged herein and the Philips-PolyTech Enterprise are separate and distinct from each other.

The racketeering activities conducted by the RICO Defendants amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the RICO Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators, and Plaintiffs. The RICO Defendants have engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Enterprise. Each of the RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in 18 U.S.C. §§ 1341 and 1343.

As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted various unlawful activities, each conducted

with the common purpose of obtaining revenue from the marketing and sale of the defective Recalled Devices. The predicate acts also had the same or similar results, participants, targeted pool of victims, and methods of commission. The predicate acts were related and not isolated.

6. **State whether the alleged predicate acts referred to above relate to each other as part of a common plan, and, if so, describe in detail the alleged enterprise for each RICO claim. A description of the enterprise shall include the following information:** The multiple acts of racketeering activity alleged in the Complaint were related to each other, pose a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

a. The names of each individual partnership, corporation, association or other legal entity which allegedly constitute the enterprise. Philips, PolyTech, and Paramount Die formed the Philips-PolyTech Enterprise.

b. A description of the structure, purpose, function and course of conduct of the enterprise. The Philips-PolyTech Enterprise came together for the common purpose to perpetuate a fraudulent scheme to conceal from patients, prescribers, TPPs, hospitals, and the FDA the true health and safety risks associated with the Recalled Devices and PE-PUR foam. This concealment was aimed to allow the Enterprise participants to profit, continue to profit, and retain profits from the sale of Recalled Devices. By knowingly concealing and minimizing the Defect, the RICO Defendants could represent the Recalled Devices as being safe and effective, while omitting information to the contrary. This false representation resulted in significant sales and revenue generated from the sale of defective Recalled Devices. Concealing and minimizing the Defect also allowed the RICO Defendants to avoid or limit the substantial costs and reputational harm associated with a recall, repair, or replacement of the Recalled Devices

The RICO Defendants, in concert with the other Enterprise participants, created and maintained systematic links toward this common purpose, *i.e.*, to manufacture, market, and sell the

Recalled Devices while concealing their health and safety risks. The Philips-PolyTech Enterprise continued for several years, beginning no later than 2015 and continuing to the present.

The RICO Defendants exerted control over the Enterprise and have coordinated and participated in the operation or management of Enterprise's affairs. At the same time, the RICO Defendants were and are separate entities existing outside the Enterprise. The RICO Defendants' independent existences are demonstrated by the following:

- During the relevant period, Philips contemporaneously designed, manufactured and sold many medical devices and products separate and apart from the Recalled Devices.
- During the relevant period, PolyTech contemporaneously sold and distributed many other noise abatement products aside from the PE-PUR foam used in the Recalled Devices.
- During the relevant period, Paramount Die contemporaneously provided cutting services for rubber, foam, plastic, and other materials apart from the PE-PUR foam used in the Recalled Devices.

The RICO Defendants also occupied delineated roles that furthered the organization's goals. Each RICO Defendant performed important but separate roles within the Philips-PolyTech Enterprise organization.

Philips participated in the conduct of the Enterprise when it, among other things:

Designed, marketed, manufactured, and sold the Recalled Devices;

- Coordinated with PolyTech to select the PE-PUR foam to use for sound abatement in the Recalled Devices;

- Downplayed, ignored, and failed to investigate issues of foam degradation in its devices using PE-PUR foam for sound abatement, including failing to perform and document required risk analyses;
- Obscured and minimized the Defect in the Recalled Devices by misleadingly blaming other factors, such as the use of ozone cleaners, when faced with recurring evidence of serious problems (*e.g.*, including consumer complaints of "black dust" and related issues);
- Communicated and coordinated regularly with PolyTech about known instances of foam degradation and consumer complaints for devices with PE-PUR foam;
- Failed to implement a preventative maintenance procedure for Trilogy ventilator devices with PE-PUR foam that was successfully instituted by another Philips entity;
- Concealed that the Recalled Devices were equipped with defective PE-PUR foam that could degrade and emit dangerous VOCs; and
- Collected revenue flowing from the sale of the Recalled Devices.

PolyTech participated in the conduct of the Enterprise when it, among other things:

- Obtained bulk PE-PUR foam from Burnett, and cut, shipped, and sold PE-PUR foam for installation in the Recalled Devices;
- Disregarded specific warnings from Burnett about PE-PUR foam, and continued to obtain and sell the defective PE-PUR foam for use in the Recalled Devices;
- Relayed communications from Philips to Burnett, including as to questions about the PE-PUR foam chemistry and the safety risks, field issues, and testing for the Recalled Devices;
- Concealed that the Recalled Devices were equipped with defective PE-PUR foam that could degrade and emit dangerous VOCs;

- Misrepresented the PE-PUR foam in the Recalled Devices to be resistant to heat and humidity;
- Communicated with Philips about known instances of foam degradation and consumer complaints for devices with PE-PUR foam; and
- Collected revenue flowing from the sale of the Recalled Devices.

In addition, each of the RICO Defendants separately ensured that the FDA, prescribers, TPPs, hospitals, and consumers did not discover the Defect in the Recalled Devices.

Without the RICO Defendants' willing participation in the conduct above, the Enterprise's scheme and common course of conduct would have been unsuccessful.

The participants' dedication of personnel to the Enterprise's scheme further evidences the ongoing structure of the Enterprise. For example,

- PolyTech dedicated its employees Bob Marsh and Bonnie Peterson to work with Philips relating to the PE-PUR foam in the Recalled Devices, and to coordinate their communications with Burnett on behalf of Philips. Ms. Peterson served as a regular point of contact for technical questions about the PE-PUR foam, while Mr. Marsh liaised with Philips' personnel on foam degradation issues and questions. Likewise, PolyTech dedicated its employee Michael Haupt to coordinate with Paramount Die.
- Philips, for its part, dedicated key personnel to the Recalled Devices' design, marketing or sale, and/or to contacting PolyTech. This included Vince Testa, who attended internal meetings on foam degradation issues and who was then designated as a point of contact for PolyTech as a follow-up to those meetings.

Establishing these regular points of contact further organized the Enterprise.

c. Whether each defendant is an employee, officer or director of the alleged enterprise. N/A, the Philips-PolyTech Enterprise is an association-in-fact Enterprise.

d. Whether each defendant is associated with the alleged enterprise. Philips and PolyTech were each associated in fact with the Philips-PolyTech Enterprise.

e. Whether it is alleged that each defendant is an individual or entity separate from the alleged enterprise, or that such defendant is the enterprise itself, or a member of the enterprise. Philips and PolyTech were each members of, and separate and distinct from, the Philips-PolyTech Enterprise.

f. If any defendant is alleged to be the enterprise itself, or a member of the enterprise, an explanation whether each such defendant is a perpetrator, passive instrument or victim of the alleged racketeering activity. N/A.

7. **State and describe in detail whether it is alleged that the pattern of racketeering activity and the enterprise are separate or have merged into one entity.** At all relevant times, the Philips-PolyTech Enterprise was separate and distinct from the pattern of racketeering in which the individual RICO Defendants engaged. *See* above "description of the structure, purpose, function and course of conduct of the enterprise."

8. **Describe the alleged relationship between the activities of the enterprise and the pattern of racketeering activity. Discuss how the racketeering activity differs from the usual and daily activities of the enterprise, if at all.** As described herein, the pattern of racketeering activity fraudulently advanced the design, manufacture, marketing, and sale of the defective Recalled Devices. RICO Defendants are in the business of designing, manufacturing, marketing, and selling medical and other devices such as the Recalled Devices. In the case of the Recalled Devices, the RICO Defendants engaged in the pattern of racketeering activity and the predicate acts in order to conceal the fact that Recalled Devices are defective and dangerous so that they could avoid the hassle and expense of a recall and continue to profit from the sale of Recalled Devices.

9. **Describe what benefits, if any, the alleged enterprise receives from the alleged**

pattern of racketeering. Each of the RICO Defendants profited, directly or indirectly, from the scheme. These profits were substantially greater than they would have been if the Defect and true risks of the Recalled Devices had been disclosed.

Philips profited directly from the sale of the Recalled Devices, which resulted from the Enterprise's deception of consumers, prescribers, TPPs, hospitals, and the FDA.

Likewise, PolyTech profited from the sale of the Recalled Devices that contained the PE-PUR foam cut and sold by PolyTech.

Paramount Die likewise profited from the sale of the Recalled Devices that contained the PE-PUR foam modified by Paramount Die for use in the Recalled Devices.

10. **Describe the effect of the activities of the enterprise on interstate or foreign commerce.** The Philips-PolyTech Enterprise engaged in and affected interstate commerce because it manufactured, marketed, sold, or provided the Recalled Devices to millions of individuals and entities throughout the United States.

11. **If the complaint alleges a violation of 18 U.S.C. § 1962(a), provide the following information:** N/A

a. The recipient of the income derived from the pattern of racketeering activity or through the collection of an unlawful debt; and

b. A description of the use or investment of such income.

12. **If the complaint alleges a violation of 18 U.S.C. § 1962(b), describe in detail the acquisition or maintenance of any interest in or control of the alleged enterprise.** N/A

13. **If the complaint alleges a violation of 18 U.S.C. § 1962(c), provide the following information:**

a. The identity of each person or entity employed by, or associated with, the enterprise. The Philips-PolyTech Enterprise included Philips and PolyTech, as well as other

nonparty individuals and corporations, including Paramount Die. Discovery will likely reveal additional members of the Philips-PolyTech Enterprise that are not currently known to Plaintiffs.

b. Whether the same entity is both the liable "person" and the "enterprise" under § 1962(c). Each RICO Defendant is and has been a liable "person" under 18 U.S.C. § 1961(3) because each was capable of holding "a legal or beneficial interest in property." The RICO Defendants came together to form the Philips-PolyTech Enterprise. At all relevant times, the Philips-PolyTech Enterprise had an existence that was separate and distinct from the individual RICO Defendants and their members. The RICO Defendants exerted control over the Enterprise and have coordinated and participated in the operation or management of Enterprise affairs. At the same time, the RICO Defendants were and are separate entities existing outside the Enterprise.

14. **If the complaint alleges a violation of 18 U.S.C. § 1962(d), describe in detail the alleged conspiracy.** The RICO Defendants have undertaken the practices described herein as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the RICO Defendants agreed to facilitate the operation of the Enterprise through a pattern of racketeering in violation of 18 U.S.C. § 1962(c), as described herein. The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Enterprise described above (*see, e.g.*, "description of the structure, purpose, function and course of conduct of the enterprise") through a pattern of racketeering activity. The RICO Defendants conspired with the Enterprise participants to manufacture, sell, and profit from the Recalled Devices while concealing their health and safety risks. The conspiracy is coterminous with the time period in which the Enterprise has existed; it began no later than 2015 and continues to this day.

The words, actions, or interdependence of activities of each RICO Defendant supports the inference of their agreement. Put another way, the RICO Defendants' agreement is evidenced by their predicate acts and direct participation in the control and operation of the Enterprise, as detailed

above in relation to the RICO Defendants' substantive violation of Section 1962(c).

The RICO Defendants' acts in furtherance of the conspiracy include each of the predicate acts underlying the RICO Defendants' violations of Section 1962(c), as described above. Various other persons, firms, and corporations, including third-party entities and individuals not named as Defendants in the Complaint, have participated as co-conspirators with the members of the Enterprise in these offenses and furthered the conspiracy to conceal the health and safety risks in the Recalled Devices to increase or maintain revenue from their sale.

The success of the Enterprise's fraudulent scheme depended upon the RICO Defendants' cooperation and agreement. These companies had to maintain strict confidentiality about the health and safety risks in the Recalled Devices or the scheme to continue. Even after learning about the health and safety risks associated with the PE-PUR foam used in the Recalled Devices, PolyTech continued to obtain the foam from Burnett and prepare it for use in the Recalled Devices. When doing so, PolyTech knew that Philips would manufacture and sell the Recalled Devices to Plaintiffs and the Class without disclosing those risks. Likewise, Philips, with knowledge of the Defect, continued to place orders that would cause PolyTech to obtain and ship PE-PUR foam for use in the Recalled Devices.

Philips depended upon PolyTech for the sourcing, cutting, and acquisition of the PE-PUR foam for the Recalled Devices, and for coordinating with Burnett to do so. On the other hand, PolyTech depended upon Philips for a viable path to profit from sale of the Recalled Devices. This interdependence evidences the agreement to further the fraudulent scheme. Where a RICO Defendant did not commit a predicate act itself, it is sufficient if it was aware of the essential nature and scope of the Enterprise such that it agreed to the commission of the foreseeable predicate acts to advance the Enterprise's goals. The actions detailed above and throughout the Complaint as to each member of the Enterprise were foreseeable to the other members of the Philips-PolyTech Enterprise given

their direct relationship to and furtherance of the common goals of the scheme.

15. **Describe the alleged injury to business or property.** The victims have been injured in their business and/or property by paying for or reimbursing payment for Recalled Devices with an undisclosed safety defect. Because of this Defect, Plaintiffs and Class members paid money for or reimbursed payment for Recalled Devices that had no actual value at the time of purchase.

16. **Describe the direct causal relationship between the alleged injury and the violation of the RICO statute.** The Philips-PolyTech Enterprise directly or indirectly obtained money from Plaintiffs and the Class by means of materially false or fraudulent misrepresentations and omissions of material facts. Had the Plaintiffs and Class members known what the RICO Defendants knew about the Recalled Devices, they would not have paid for or reimbursed payment for the Recalled Devices. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused injury to Plaintiffs' and Class members' business and property. The RICO Defendants' pattern of racketeering activity logically, substantially, and foreseeably caused TPPs, hospitals, and consumers to pay for or reimburse payment for the Recalled Devices. The injuries suffered by the Plaintiffs and Class members were not unexpected, unforeseen, or independent. Rather, the RICO Defendants knew that the Recalled Devices were defective and unsafe. Regardless of these known risks, the RICO Defendants used mail and wires to carry out their scheme of deception, thereby reaping increased profits. Had the RICO Defendants disclosed their knowledge of the Defect in the Recalled Devices and informed the FDA and the public, Plaintiffs would have learned of the disclosure and made informed decisions about the health and safety risks of the Recalled Devices. The Enterprise's misleading statements and omissions to the FDA and to prescribers were essential to the scheme. The FDA would have considered information about the defective PE-PUR foam material (as evidenced by its Class I classification of the ongoing recall), and prescribers would not have prescribed dangerous and defective breathing machines to their

patients. At the very least, the RICO Defendants' misleading statements delayed the FDA's broader investigation of the Recalled Devices. The RICO Defendants knew that their concealment of the risks would cause Plaintiffs and the Class to pay for or reimburse payment for the Recalled Devices and to suffer the attendant harms and safety risks of breathing through machines with defective and toxic foam.

17. **List the damages sustained by each plaintiff for which each defendant is allegedly liable.** Plaintiffs and Class members have suffered injuries as a result of their purchase, lease, or reimbursement of payment for the Recalled Devices, including substantial economic losses related to their payment or reimbursement of payment for the Recalled Devices and accessories, and replacement machines and accessories, and losses from not being able to use their machines, and other consequential damages. Plaintiffs and Class members seek the above-described actual damages, as well as treble damages and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq*. Plaintiffs reserve the right to supplement their damages theory(ies) as fact and expert discovery proceeds.

18. **List all other federal causes of action, if any, and provide the relevant statute numbers.**

Magnuson-Moss Federal Warranty Act 15 U.S.C. § 2301, *et seq.*

19. **List all pendent state claims, if any.**

Breach of express warranty, breach of the implied warranty of merchantability, breach of the implied warranty of usability, common law fraud, unjust enrichment, and state consumer protection statutes, all brought under the laws of each of the 50 states and the District of Columbia.

20. **Provide any additional relevant information that would be helpful to the court in processing the RICO claim.**

None at this time.

* * *

Plaintiffs reserve the right to supplement the foregoing as fact and expert discovery proceeds.

Dated: October 24, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 24th day of October 2022 and is available for download by all counsel of record.

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